DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 12, 2015

Medela AG
% Ms. Adrienne Lenz
Pathways Regulatory Consulting, LLC
W324 S3649 County Road East
Dousman, Wisconsin 53118

Re: K142626
Trade/Device Name: Invia Liberty Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: May 11, 2015
Received: May 12, 2015

Dear Ms. Lenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142626

Device Name
Invia Liberty Negative Pressure Wound Therapy System

Indications for Use *(Describe)*
The Medela® Invia Liberty Negative Pressure Wound Therapy System is indicated to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

DATE: June 11, 2015

SUBMITTER:

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Orlando Atunes
Vice President Regulatory Affairs
Medela AG

DEVICE:

TRADE NAME: Invia Liberty Negative Pressure Wound Therapy System

COMMON/USUAL NAME: Negative Pressure Wound Therapy Pump and Accessories

CLASSIFICATION NAMES: 21 CFR 878.4780 Powered Suction Pump

PRODUCT CODE: OMP

PREDICATE DEVICE(S):

K080357 Invia Wound Therapy

DEVICE DESCRIPTION:

The Medela Invia Liberty Negative Pressure Wound Therapy (NPWT) System is comprised of the Invia Liberty NPWT Pump, canister/tubing set, power supply, carrying case, patient and user instructions, and Invia NPWT kits. The Invia Liberty is also compatible with Avance NPWT kits manufactured by Mölnlyke Healthcare.

The Invia Liberty NPWT pump is a suction pump for Negative Pressure Wound Therapy with an optical and acoustic status display. Acoustic and optical signals are triggered for variances from the set values as well as for faults. The Invia Liberty NPWT pump provides continuous or intermittent operation.

The Invia Liberty NPWT system may be used in a home or other health care facility by medical personnel or trained lay users adhering to the instructions for use. The user may not be hard of hearing or deaf and must have normal visual acuity. The Invia Liberty NPWT pump is portable and can be operated independent of the electrical power supply via its rechargeable battery.

INTENDED USE:

The Medela® Invia Liberty Negative Pressure Wound Therapy System is indicated to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The Invia Liberty NPWT System uses the same fundamental technology as Invia Wound Therapy (K080357) for most features. The Invia Liberty NPWT System is identical to the Invia Wound Therapy in its indications for use and contraindications. The main differences between the Invia Liberty NPWT System and the predicate Invia Wound Therapy are:

- New double lumen pump tubing with quick connector coupling. The smaller lumen (air flush tubing) flushes air to remove exudate from the larger lumen. Larger lumen (suction tubing) removes the fluid from the wound into the canister. The quick connector will ensure that the connection is easy to connect / disconnect and tight.
- New Drain Adapter to connect quick connect tubing to drains
- New Y-Connector for quick connect compatibility
- Firmware change, including improved flush algorithm
- Housing material change to ABS to improve the stability and cleanability
- Additional IFU for patient in home care environment

The table below summarizes the key specifications of the Invia Liberty NPWT System and the predicate devices.

	Invia Liberty Negative Pressure Wound Therapy System	**Invia Wound Therapy (K080357)**	**Discussion**
Patient Population	Adults	Adults	Identical. Pumps are reusable and should be cleaned and disinfected between patients.
Useful Life	4000 hours	4000 hours	Identical
Environment of Use	Hospital and Home	Hospital and Home	Identical
User Interface	Five button keypad (power and arrow keys to navigate menus), LCD Display, audio indicators.	Five button keypad (power and arrow keys to navigate menus), LCD Display, audio indicators.	Identical
Accessories	• Disposable Canister 0.8 l, 0.3 l • Quick connect double lumen tubing set • Drain Adapter • Y-connector • Mains adapter • Docking station • Carrying Case • Holder with standard rail • NPWT kits sold separately	• Disposable Canister 0.8 l, 0.3 l • Tubing set • Y-connector • Mains adapter • Docking station • Carrying Case • Holder with standard rail • NPWT kits sold separately	Equivalent. The tubing set is modified with a double lumen and Quick Connector coupling between the pump tubing and the drain adapter, which now connects to the Dressing Kits. All other accessories are identical.
Specifications			
Suction capacity liters/min	5 l/min	5 l/min	Identical

	Invia Liberty Negative Pressure Wound Therapy System	Invia Wound Therapy (K080357)	Discussion
Max. vacuum mmHg/kPa	- 200mmHg -27kPa	- 200mmHg -27kPa	Identical
Min. vacuum mmHg/kPa	- 40mmHg -5.3kPa	- 60mmHg -8kPa	Equivalent. Minimum vacuum level changed to -40mmHg to enable therapy for sensitive wounds (i.e. burns)
Therapy modes	Continuous & Intermittent	Continuous & Intermittent	Identical
Canister capacity [ml]	300/800ml	300/800ml	Identical
Weight [kg]	1.0kg	1.0kg	Identical
Dimensions mm	290x95x235mm (0.3l canister)	290x95x235mm (0.3l canister)	Identical
Standard Safety device	Bacteria / overflow / protection filter	Bacteria / overflow / protection filter	Identical
NPWT Kits	Multiple available including the following	Multiple available including the following	
Dressing (to pack the wound)	Kerlix AMD Gauze or Molnlyke foam	Kerlix AMD Gauze	Equivalent. Gauze Kits used with Invia Liberty and Invia Motion pumps are cleared in K113678. Molnlycke foam kits are cleared in K141847.
Sterile Saline	Winchester Laboratories Sodium Chloride 0.9%w/v	Winchester Laboratories Sodium Chloride 0.9%w/v	Identical
No sting barrier film	3M Cavilon No Sting Barrier Film	3M Cavilon No Sting Barrier Film	Identical

	Invia Liberty Negative Pressure Wound Therapy System	Invia Wound Therapy (K080357)	Discussion
Contact layer	3M Tegaderm Contact (OEM labeled)	3M Tegaderm Contact (Medela labeled)	Equivalent. Only the labeling has changed. The kits now include original 3M labeling.
Dressing to seal the wound	3M Tegaderm Film (OEM labeled)	3M Tegaderm Film (Medela labeled)	Equivalent. Only the labeling has changed. The kits now include original 3M labeling.
Additional drain seal material	Coloplast Stoma Paste	NA	Equivalent. The Coloplast Stoma Paste is used to fill crevices or uneven surfaces to improve seal in difficult to dress areas.
Tape	HyTape	HyTape	Identical
Drains	Round channel (15 Fr), Flat (10 mm), External Suction Interface (ESI)	Round channel (15 Fr), Flat (10 mm)	Equivalent. Drains, including ESI, are cleared via K113678 for use with Invia Motion and Invia Liberty pumps. Selection of drain is made by the health care provider.

SUMMARY OF NON-CLINICAL TESTS:

The Invia Liberty Negative Pressure Wound Therapy System complies with voluntary standards for electrical safety, electromagnetic compatibility, and safety of home use devices. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Software Validation
- Hardware Integration Testing
- Electrical safety and electromagnetic compatibility testing per IEC 60601-1 and IEC 60601-1-2 standards, respectively

- Safety testing for use in the home per IEC 60601-1-11 standard
- Usability evaluation per the IEC 60601-1-6 and IEC 62366 Standards.
- Performance Testing demonstrating the functionality of the Invia Liberty pump in combination with the Medela Invia Gauze Kits and Avance Foam Kits. Testing with the gauze kits included use of the double lumen tubing and drain adaptor and testing of the foam kits also used with double lumen tubing with the Avance ViewPad.
- Testing of the quick connector demonstrating adequate tightness and tear-out force.
- Biocompatibility testing, including cytotoxicity, sensitization, irritation.
- Validation of cleaning methods for the reusable pump housing.
- Sterilization validation and confirmation of shelf life for the sterile tubing, Y-connector and drain adapter.

SUMMARY OF CLINICAL TESTS:

The Invia Liberty Negative Pressure Wound Therapy System has not been the subject of clinical testing.

CONCLUSION:

Medela AG considers the Invia Liberty Negative Pressure Wound Therapy System to be as safe as, as effective as, and substantially equivalent to the predicate devices.